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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STICE, PAULA J

ART UNIT

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3766

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,366	Applicant(s) DUBI, SHAY	
	Examiner PAULA J. STICE	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/06/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/28/2006; 04/06/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Regarding claim 1: the claim recites "the imaginary surface" in line 10. It is unclear what an "imaginary surface" would be with respect to a device. The term "imaginary" is unclear and vague. This could be in relation to any surface.
4. Regarding claim 8: The claim recites "attached to the external ventricular wall during the end diastolic period of the cardiac cycle". This language is vague and unclear, with specific reference to the term "attached". This language could indicate an operational procedure of physically attaching the device during the end diastolic period or it could be indicative of the air-impermeable sheet being physically attached and in contact with the external wall during the end stages of diastole.
5. Regarding claim 10: The claim recites "a fabric patch girdle" in line 3. It is unclear what this fabric patch girdle actually is or pertains to. Furthermore, the specification lacks enough information to distinctly point out what this fabric patch girdle is.
6. There is insufficient antecedent basis for these limitations in the following claims:

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a. Claim 1 recites the limitations: The claim recites in the preamble “of either the left or right ventricle of the heart comprising:” There is insufficient antecedent basis. It is suggested that this language is replaced with preamble “of either a left or right ventricle of a heart comprising:” Furthermore, by amending this antecedent basis issue it will elevate some of the antecedent basis issues that persist in the claim and are outlined below.

- “the external ventricular surface” in lines 6-7, 13-14 and line 22; “the heart” in lines 7 and 22; “the imaginary surface” in line 10; “the perimeter” in line 10; “the lower surface” in lines 14-15; “said external ventricular surface” in lines 15-16; “said closed empty space” in lines 18-19; “the volume” in lines 19-20; “said space” line 20; “the course” line 20; “the cardiac cycle” lines 20-21

7. Claim 6 recites the limitations: “of the left and/or right ventricles of the heart”, in the preamble it is suggested that this be replaced with “of a left and/or right ventricle of a heart”. This will elevate some of the antecedent basis issues below.

- “the external surface” in lines 3-4; “the left ventricle” in line 4; “the peripheral margin” in lines 6-7; “the external ventricular wall” in lines 7 and 9; “the space” in line 8.

8. Claims 8 -10 recites the limitation: “the external ventricular surface” .

9. Claim 11 recites the limitations: “the maximal value” in lines 2-3; “the normally-outward expansive pressure” in line 3; “the external ventricular wall” in line 4.

10. Claim 12 recites the limitations: “the ventricle” in lines 1-2; “the left ventricle” in line 2.

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11. The remainder of the claims are also rejected in that they depend on previously rejected independent claims 1 and 6.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Grooters (US 5,131,905).

14. Regarding claim 1 (as understood): Grooters discloses at least one air-impermeable sheet 31 ("membrane", Fig's 3-5) that is capable of being operatively connected to an external ventricular surface of a heart (Fig's 3-5) by means of one or more connecting elements 48 ("strap or band", Fig's 3-5), wherein the sheet is curved or angled ("membrane 31 is secured to the shell", Col. 2, lines 54-55 - it is noted that the shell is curved see Fig's 3-5), such that a hollow space 33 ("inflatable space", Fig. 5) exists between the sheet and is contacting the parameter of the sheet (Col. 2, lines 48-67), such that when the air-impermeable sheet is operatively connected to the external ventricular surface of the heart, a closed empty space is created between the lower surface of the sheet and the external ventricular surface ("Membrane 31 is secured to shell 30 around the upper perimeter edge of the shell so as to define an inflatable space 33 which can be filled with liquid or gas through supply hose 35", Col. 2, lines 54-56), such that the air-impermeable sheet is capable of creating a sub-atmospheric pressure

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within said closed empty space as a consequence of changes in the volume of the empty space during the course of the cardiac cycle (Col. 3, lines 52-55), thereby exerting an outward and normally directed force on the external ventricular surface of the heart to which said air-impermeable sheet is connected by connecting elements (Col. 2 lines 4-17 and 48-62).

15. Regarding claim 3 (as understood): Grooters discloses a rigidity-determining element 30 ("non-distensible shell", Fig's 3-5)

16. Regarding claim 4 (as understood): Grooters discloses wherein the air-impermeable sheet is in the form of a convex shaped rigid element with a plurality of laterally-disposed rigidity-determining elements ("membranes" Col. 2, lines 48-65).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grooters (US 5,131,905) in view of Snyders (US 4,690,134).

19. Regarding claim 2: Grooters discloses the invention of claim 1. However, Grooters does not expressly disclose that the air-impermeable sheet is a biocompatible polymeric material. Snyders teaches of a ventricular assist device with a flexible shell (abstract) the shell is made of a highly flexible elastic biomedical elastomeric membrane. It is noted that an elastomeric material is inherently a polymer in that it is an

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elastic polymer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grooters to include the use of a biocompatible polymeric material, as taught by Grooters, for the purpose of having a highly elastic material which can move with the cardiac cycle.

20. Claims 5-8 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grooters (US 5,131,905) in view of Anstadt et al. (US 2004/0267086).

21. Regarding claim 5 (as understood): Grooters discloses the invention of claim 1. However Grooters does not disclose the use of a one-way valve inserted into the air-impermeable sheet. Anstadt however discloses a cardiac assist device which has an external component attached to the ventricular surface of a heart (abstract) in which a one-way valve is used in order to prevent fluids from passing into the shell. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grooters to include the use of a one-way valve, as taught by Anstadt, for the purpose of allowing access into the inner chamber of the air-impermeable sheet ("cup" pg. 0370) without allowing for fluid flow into the chamber.

22. Regarding claim 6 (as understood): Grooters discloses attaching an air-impermeable sheet to an external surface of a the heart i.e. both ventricles (abstract and Fig's 1 and 4), ascertaining that air-tight sealing of a peripheral margin of the sheet to the external ventricular wall has occurred (Col. 3, lines 40-55). However Grooters does not disclosed draining fluid and solid debris from the space formed between one

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surface of the sheet and the external ventricular wall through drainage means fitted in said sheet to a region located outside of the sheet. Anstadt however teaches of a ventricular assist device which as inflatable means 116/118 (Fig 2C) which operatively aid in the flow of blood. Anstadt further teaches aspirating fluids from within the volumes of the inner chambers 51/53 (Fig's 2L and 2M) via drainage grooves on the interior the fluid is shunted outside of the shell (pg. 0589). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grooters to include the use of removing fluid and debris built up due to operational miscalculations, as taught by Anstadt, for the purpose of allowing for the device to perform optimally.

23. Regarding claim 7 (as understood): Grooters as modified by Anstadt discloses the invention of claim 6: However, Grooters/Anstadt does not specifically disclose a one-way valve. Anstadt further teaches of the drainage means as a one-way valve connected to one or more tubes (pg. 0590 and 0305). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grooters to include the use of removing fluid and debris built up due to operational miscalculations, as taught by Anstadt, for the purpose of allowing for the device to perform optimally.

24. Regarding claim 8 (as understood): Grooters as modified by Anstadt discloses the invention of claim 6: Grooters/Anstadt does not specifically disclose that the air-impermeable sheet is attached to the external ventricular wall during the end diastolic period of the cardiac cycle. Grooters however discloses that the membrane is completely engaged with the heart (Col.2, lines 57-58). This would be indicative of

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being attached during the end diastolic period of the cardiac cycle in that it is always in contact with the surface of the heart.

25. Regarding claim 11 (as understood): Grooters as modified by Anstad discloses the invention of claim 6. However Grooters/Anstad does not disclose a ventricular wall pressure between 5 mm Hg and 40 mm Hg. Anstadt further teaches of delivering 20 mm Hg initial pressure (pg. 0362) It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grooters/Anstad to include a pressure value of 20 mm Hg, as taught by Anstad, for the purpose of adjusting the pressure to maintain physiological parameters.

26. Regarding claim 12 (as understood): Grooters as modified by Anstad discloses the invention of claim 6. Grooters as well as Anstad both disclose treating the left ventricle: Grooters (abstract) and Anstadt (pg. 0065).

27. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grooters (US 5,131,905) in view of Anstadt et al. (US 2004/0267086) and further in view of Snyder (US 4,690,134).

28. Regarding claim 9: Grooters as modified by Anstadt discloses the invention of claim 6, however Grooters/Anstadt does not specifically disclose the use of attaching the air-impermeable sheet via surgical sutures. Snyder however discloses a cardiac assist device which is surgically sutured using to the pericardial wall (Col. 4, lines 35-40). It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to modify Grooters/Anstadt to include the use of surgical sutures, as taught by Snyder, for the purpose of securing the device to the cardiac wall.

29. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grooters (US 5,131,905) in view of Anstadt et al. (US 2004/0267086) and further in view of Alferness (US 5,702,343).

30. Regarding claim 10 (as understood): Grooters as modified by Anstadt discloses the invention of claim 6. However Grooters/Anstadt does not specifically disclose the use of patches as attachment means. Alferness however teaches of using Dacron (TM) patches to repair cardiac ruptures and septal defects (Col. 1, lines 30-35). Alferness further teaches of a girdle type construction ("cardiac CRD jacket" figure number 15 in Fig. 3), which is a mesh material (Col. 6, lines 29-35) which can be a polymer mesh (claim 11) or a polyester mesh (claim 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grooters/Anstadt to include the use of patches as an attachment means, as taught by Alferness, for the purpose of securing the device to the cardiac wall with a biomaterial which elicits very little immune reaction upon chronic implantation.

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31. Claim 10 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Grooters (US 5,131,905) in view of Anstadt et al. (US 2004/0267086) and further in view of Feld et al. (US 2004/0002626).

32. Regarding claim 10 (as understood): Grooters as modified by Anstadt discloses the invention of claim 6. However Grooters/Anstadt does not specifically disclose the use of a fabric patch girdle as attachment means. Feld however discloses the use of a fabric patch girdle system (pg. 0218). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Grooters/Anstadt to include the use of a fabric patch girdle system, as taught by Feld, for the purpose of securing the device to the surface of the heart.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Melvin (US 6,592,619) – discloses a heart wall actuation device.
- Yadav et al (US 2004/0092790) – discloses a hydraulically actuated artificial muscle device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAULA J. STICE whose telephone number is (571) 270-1478. The examiner can normally be reached on Monday - Friday 8AM-5PM, Est., alternating Friday's.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3766

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